## REMARKS

Claims 3, 7 and 10 are pending after entry of this paper. Claims 1-2, 4-6, 8, 9, and 11-28 have been cancelled without prejudice. Applicants reserve the right to pursue withdrawn and cancelled claims in a divisional or continuing application.

Claim 3 has been amended to delete the phrases related to the objected term "about" and the number of amino acid residues. Also, the phrases "and an immunologically functional analog thereof" and "or deleted" have been cancelled. As requested by the Examiner, functional language has been added. Specifically, the phrase "wherein the synthetic peptide induces anti-IgE antibody production in a mammal" has been added. Support may be found in the instant specification and claims as original filed. No new matter has been presented by these amendments.

Applicants wish to thank Examiners Rooney and Haddad for allowing us an interview after Final Rejection and for the courtesies extended in the telephonic interview on March 21, 2008. Applicants wish to specifically thank the Examiners for taking the time to review and consider the proposed claim amendments and the enablement and written description rejection thereto.

Response to Rejections under 35 U.S.C. §112, Second Paragraph

Claim 3 stands and claims 7 and 10 are rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite with respect to the phrases, "about 50 to about 90 amino acids," "about 25 to about 29 amino acids," and "about 23 amino acid residues." The Examiner finds the term "about" unclear with respect to how many amino acids "about" constitutes.

Although applicants respectfully disagree with the Examiner's contention, in order to expedite prosecution and without disclaimer of or prejudice to the subject matter recited therein, applicants have amended claim 3 to delete the term "about" in order to address the Examiner's concerns. Applicants respectfully request reconsideration and withdrawal of the indefiniteness rejection to claims 3, 7, and 10.

The Office Action objects to the term "SSAL" in claim 7 because the term is indefinite and arbitrarily designates the helper T cell epitope. Applicants respectfully disagree. On page 14, line 29- page 15, line 29, a helper T cell epitope (Th) that is an SSAL epitope is constructed based on guidelines, particularly with respect to amino acid residue charges, hydrophobicity, etc. in order to "enlarge the range of immune responsiveness to an artificial Th." However, in order to expedite prosecution and without disclaimer of or prejudice to the subject matter recited therein, applicants have amended claims 7 and 10 to read "helper T cell epitope" and/or "SSAL epitope." Applicants respectfully request reconsideration and withdrawal of the indefiniteness rejection to claim 7.

Response to Rejections under 35 U.S.C. §112, First Paragraph

Claims 3, 7 and 10 have been rejected under 35 U.S.C. §112, first paragraph for allegedly lacking enablement for the claimed invention. Specifically, the Examiner contends that a synthetic peptide of about 50 to about 90 amino acids having a helper T cell epitope; an IgE-CH3 domain antigen peptide between about 25 and about 29 amino acids in length, which contains two Cysteine residues separated by about 23 amino acid residues, and has a sequence of SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:8 or SEQ ID NO:84 and an immunologically

functional analog thereof, where from one to four of the residues in SEQ ID NO: 5 is conservatively substituted or deleted, is not enabled for any person skilled in the art to make or use the invention. Applicants respectfully disagree.

However, in order to expedite prosecution and without disclaimer of or prejudice to the subject matter recited therein, applicants have deleted the objected phrase, "of about 50 to about 90 amino acids." Moreover, the term "about" has been deleted throughout the claims. Furthermore, "an immunologically functional analog" has been deleted. Thus, the enablement rejection is moot.

With respect to the Examiner's contention that the specification does not support "helper T cell epitope (Th)," applicants respectfully disagree. The skilled artisan having read the instant specification would understand what was meant by helper T cell epitope. As previously asserted, the instant specification provides sufficient support for the skilled artisan to make and use the invention since structural and functional information of the helper T cell epitope are provided in the instant specification at pages 13-14 and 26-27. As disclosed on page 11 of the instant specification, immunogenicity of a B cell target epitope is augmented by combining it with a peptide having a broadly reactive promiscuous T helper cell epitope. Page 36 describes several different Th sites that are exemplified in Tables 4, 5, and 6 of the instant invention. However, in order to expedite prosecution and without disclaimer of or prejudice to the subject matter recited therein, applicants have, upon the Examiner's suggestion during the telephonic interview, amended claim 3 such that the helper T cell epitope is directed to a promiscuous epitope.

Applicants believe that the claims as presented herein are enabled to such an extent that the skilled artisan would have sufficient guidance and knowledge to make and use the

invention. Therefore, applicants respectfully request reconsideration and withdrawal of the § 112, 1st paragraph rejections.

Claim 3 stands and claims 7 and 10 are rejected under 35 U.S.C. §112, first paragraph for allegedly lacking written description to convey to one of skill in the art that the inventors were in possession of a synthetic peptide of about 50 to about 90 amino acids, having a helper T cell epitope; an IgE-CH3 domain antigen peptide between about 25 and about 29 amino acids in length, which contains two Cysteine residues separated by about 23 amino acid residues, and has a sequence of SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:8 or SEQ ID NO:84 and an immunologically functional analog thereof, where from one to four of the residues in SEQ ID NO: 5 is conservatively substituted or deleted. As previously indicated, the objected phrases, "about 25 to about 90 amino acids," "between about 25 and about 29 amino acids in length," "about 23 amino acid residues," and "immunologically functional analog thereof" have been deleted without prejudice.

The Examiner admits that applicants are in possession of the synthetic peptides of SEQ ID NOs:14-15, 17-23, and 85 (Office Action- page 11). Applicants assert that one to four **residues of the IgE-CH3 domain** antigen peptide of SEQ ID NO:5 may be conservatively substituted and maintain functionality. For example, the synthetic peptides with an **IgE-CH3 domain** having conservatively substituted amino acids of SEQ ID NO:5 (*e.g.*, SEQ ID NO:18) were demonstrated to have crossreactivity with human IgE and their anti-IgE antibodies which were capable of inhibiting histamine release (see, Tables 2, 4B). Applicants assert that the instant specification adequately describes the claimed invention as supported by the Examples

and resulting data. Reconsideration and withdrawal of the alleged lack of written description are respectfully requested.

## CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and entry of the listing of claims presented herein, and furthermore, withdrawal of the rejection of claims and allowance of this application. Favorable action by the Examiner is earnestly solicited.

## AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **13-4500**, Order No. 1151-4153US2.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **13-4500**, Order No. 1151-4153US2.

Respectfully submitted,
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